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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/979,518

04/10/2002

Judith E Meis

310307.90134

6310

7590

02/27/2009

Jean C Baker
Quarler & Brady
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

02/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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DETAILED ACTION

Claims 60, 61, 63, 64, 66 and 67 are present and at issue for examination.

Applicants' arguments filed on 12/2/2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60, 61, 63, 64, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche Molecular Biochemicals Catalog, 1999, pages 50-51, See IDS, Sellman et al. Journal of Bacteriology, Vol 174, No. 13, pages 4350-4355, see IDS, July 1992, Lu et al. BioFeedback, Vol 11, No. 4, pages 464-466, 1991, See IDS.

This rejection was stated in the previous office action as it applied to previous claims 60, 61, 63, 64, 66 and 67. In response to this rejection, applicants have not amended the claims, but rather traverse the rejection as it applies to the claims.

Applicants submit that as previously amended, the claims of the current application recite the DNA polymerase from *Bacillus stearothermophilus* (*Bst*) type strain 5, in contrast, to the DNA polymerase described in the Roche catalog which is

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from a different organism, *Carboxydotherrnus hydrogenoformans*. Applicants submit that nothing in Roche, Sellman or Lu teach or suggest that replacing the *Carboxydotherrnus hydrogenoformans* with *Bacillus stearothermophilus* (Bst) type strain 5 will be feasible, let alone successful. Applicants submit that in contrast, those with knowledge in the art will understand that particular enzymatic activities, properties and reaction conditions vary for each different enzyme and, based on the present knowledge in the art, the properties of a DNA polymerase from *Carboxydotherrnus hydrogenoformans* cannot be used to predict the activities, properties, or reaction conditions for using another enzyme from another source for a particular application.

In response, while it is appreciated that the skilled artisan would understand that different enzymes from different sources would have different activities, properties or optimum reaction conditions, it would also be understood that many of the activities, properties and reaction conditions overlap and are related, especially in the DNA polymerase family. Applicants are reminded that as previously stated, Roche Molecular Biochemicals Catalog, 1999 teach that while other thermoactive DNA polymerase with reverse transcriptase activity use manganese ions as co-factors, manganese has a negative effect on the fidelity of DNA synthesis. This knowledge in combination with the teaching of Spellman et al. who specifically teach the DNA polymerase enzymes from *Bacillus Stearothermophilus* require Mg^{2+} for optimal activity, certainly provides a basis for overlap of reaction conditions, if not over lap of optimal reaction conditions. Thus the combination of the teachings of Roche Molecular Biochemicals Catalog, 1999 and Sellman et al. provides the motivation to practice similar methods with similar reaction

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conditions for the two magnesium dependent DNA polymerases, especially with regard to the presence of magnesium and the absence of manganese.

Applicants comments referring to "For example, the organization of *Bacillus stearothermophilus* (*Bst*) type strain 5 provides at least three different DNA polymerase from *Thermus* species, including *Thermus aquaticus* (Taq) DNA polymerase, *Thermusflavus* (Tfl) DNA polymerase, and *Thermus thermophilus* (Tth) DNA polymerase. Of these three *Thermus* enzymes, only the Tth DNA polymerase can be used for reverse transcription and this enzyme requires manganese ions for this use." are somewhat confusing and interpreted as applicants are pointing out that as above different enzymes have different activities, properties and reaction conditions. As above, it is appreciated that one of skill in the art would realize this, however, as pointed out above, given the teachings of Roche Molecular Biochemicals Catalog, 1999 and Sellman et al., as repeated above, one of skill in the art would have been motivated to practice similar methods with similar reaction conditions for the two magnesium dependent DNA polymerases, especially with regard to the presence of magnesium and the absence of manganese. Given these teachings, the finding by the Applicant that the *Bacillus stearothermophilus* (*Bst*) type strain 5 DNA polymerase had reverse transcriptase activity in the presence of magnesium and in the substantial absence of manganese ions is not considered surprising and unexpected.

Applicants further submit whether or not a DNA polymerase has RNA-template-dependent DNA synthesis (or reverse transcriptase) activity and, if a DNA polymerase does also have reverse transcriptase activity, the fact that it has DNA-dependent DNA

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polymerase activity in the presence of only magnesium ions without any manganese ions does not indicate that it will have reverse transcriptase activity in the presence of magnesium ions and the absence of manganese ions. While this argument is appreciated and may be true, though this property may not be guaranteed, it is considered more likely than not given the previous teachings of the above references, as emphasized above. The combination of the teachings of

Roche Molecular Biochemicals Catalog, 1999 that while other thermoactive DNA polymerase with reverse transcriptase activity use manganese ions as co-factors, manganese has a negative effect on the fidelity of DNA synthesis. This knowledge in combination with the teaching of Spellman et al. who specifically teach the DNA polymerase enzymes from *Bacillus Stearothermophilus* require Mg^{2+} for optimal activity, certainly provides a basis for overlap of reaction conditions, if not overlap of optimal reaction conditions for reverse transcriptase activity. Thus the combination of the teachings of Roche Molecular Biochemicals Catalog, 1999 and Sellman et al. provides the motivation to practice similar methods with similar reaction conditions for the two magnesium dependent DNA polymerases, especially with regard to the presence of magnesium and the absence of manganese.

Thus, claims 60, 61, 63, 64, 66 and 67 remain obvious over Roche Molecular Biochemicals Catalog, 1999, Sellman et al. and Lu et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg
2/24/2009

/Richard G Hutson/
Primary Examiner, Art Unit 1652